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II

106TH CONGRESS  
1ST SESSION

## S. 1542

To amend the Federal Food, Drug, and Cosmetic Act to require any person who reprocesses a medical device to comply with certain safety requirements, and for other purposes.

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### IN THE SENATE OF THE UNITED STATES

AUGUST 5, 1999

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require any person who reprocesses a medical device to comply with certain safety requirements, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This title may be cited as the "Reprocessed Single  
5 Use Medical Device Patient Safety Amendments of 1999".

1 SEC. 2. REPROCESSED MEDICAL DEVICES.

2 Subchapter A of chapter V of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
4 ed by adding at the end the following:

5 "SEC. 524. REPROCESSED MEDICAL DEVICES.

6 "(a) FINDINGS.—Congress makes the following find-  
7 ings:

8 "(1) The Food and Drug Administration has  
9 information indicating that some reprocessed med-  
10 ical devices labeled for single use have been associ-  
11 ated with serious injury and that reprocessed med-  
12 ical devices labeled for single use have the potential  
13 to cause injury.

14 "(2) Reprocessed medical devices labeled for  
15 single use are being used on patients without their  
16 knowledge, against original manufacturers' warn-  
17 ings, and without a determination by the Food and  
18 Drug Administration that such devices are safe and  
19 effective.

20 "(3) The reprocessing of devices that are la-  
21 beled for single use is currently occurring without  
22 premarket approval by or notification to the Food  
23 and Drug Administration, such as is required for  
24 certain devices under sections 510 and 515.

25 "(4) The Food and Drug Administration should  
26 have the knowledge and expertise to evaluate the

1 safety and effectiveness of reprocessed medical de-  
2 vices labeled for single use.

3 “(5) Enforcement by the Food and Drug Ad-  
4 ministration of the provisions of this Act that ad-  
5 dress the safety and effectiveness of devices is the  
6 only effective way to protect patients exposed to re-  
7 processed medical devices labeled for single use.

8 “(6) The United States public deserves to know  
9 that all devices regulated by the Food and Drug Ad-  
10 ministration are safe and effective and that the ap-  
11 propriate level of oversight is being implemented in  
12 order to guarantee such safety and effectiveness.

13 “(b) PURPOSE.—The purpose of this section is to—

14 “(1) require that the Food and Drug Adminis-  
15 tration implement all provisions of this Act that are  
16 applicable to reprocessed medical devices, including  
17 device registration, listing, and premarket safety  
18 controls; and

19 “(2) require the informed consent of patients  
20 prior to using reprocessed class II and class III  
21 medical devices.

22 “(c) REGISTRATION.—Every person or establishment  
23 engaged in the reprocessing of a device labeled for single  
24 use shall—

1           “(1) upon first engaging in the reprocessing of  
2       such device, register with the Secretary and provide  
3       all information required in accordance with section  
4       510(c);

5           “(2) for each year in which the person or estab-  
6       lishment engages in the reprocessing of such device,  
7       register with the Secretary and provide all informa-  
8       tion required under section 510(b); and

9           “(3) for each year in which the person or estab-  
10      lishment engages in the reprocessing of such device,  
11      submit to the Secretary a list of devices labeled for  
12      single use that the person or establishment is re-  
13      processing, including the names of the original  
14      equipment manufacturers of such devices and the  
15      specific models of such devices that are reprocessed.

16          “(d) INFORMATION.—Every person or establishment  
17      engaged in the reprocessing of a device labeled for single  
18      use shall, for each reprocessed medical device, provide to  
19      each person or establishment that uses such reprocessed  
20      medical device, information necessary for such person or  
21      establishment to comply with subsection (f).

22          “(e) SAFETY AND EFFECTIVENESS.—Every person  
23      or establishment required to register under subsection (c)  
24      with respect to a device shall demonstrate to the Secretary  
25      that such reprocessed device is safe and effective or sub-

1   stantially equivalent to a device the Secretary has deemed  
2   safe and effective. The Secretary may exempt class I de-  
3   vices from the requirements of this subsection.

4       “(f) INFORMED PATIENT CONSENT AND MEDICAL  
5   RECORDS.—

6       “(1) IN GENERAL.—Every person or establish-  
7       ment that uses a class II or class III reprocessed  
8       medical device to provide medical care to an indi-  
9       vidual shall seek informed consent from the patient  
10      for the use of such a device.

11      “(2) MEDICAL RECORDS.—

12          “(A) IN GENERAL.—Every person or es-  
13          tablishment that uses a class II or class III re-  
14          processed medical device to provide medical  
15          care to an individual shall keep a record of such  
16          use and include a note of such use in such indi-  
17          vidual’s medical record.

18          “(B) CONTENTS.—The contents of the  
19          record described in paragraph (1) shall  
20          include—

21              “(i) the name and place of business of  
22              the person or establishment that reproc-  
23              essed the device labeled for single use and  
24              the batch or lot number of such device;  
25              and

1                   “(ii) the identity of the original manu-  
2                   facturer of the device.

3           “(g) REPORT.—Not later than 9 months after the  
4 date of enactment of this section, the Secretary shall sub-  
5 mit a report to the Committee on Commerce of the House  
6 of Representatives and the Committee on Health, Edu-  
7 cation, Labor, and Pensions of the Senate that describes  
8 findings from current Food and Drug Administration  
9 studies (as of the date of submission) on the safety and  
10 efficacy of reprocessing of devices labeled for single use.

11          “(h) MEDWATCH.—Not later than 6 months after the  
12 date of enactment of this section, the Secretary shall mod-  
13 ify the MEDWATCH forms to facilitate reporting of infor-  
14 mation relating to reprocessed medical devices, including  
15 the name of a reprocessor and the number of times a de-  
16 vice has been reused.

17          “(i) APPLICATION.—All other sections of this Act  
18 that govern devices as defined in section 201(h) shall also  
19 apply to reprocessed medical devices, if applicable.

20          “(j) DEFINITIONS.—In this section:

21               “(1) REPROCESSED MEDICAL DEVICE.—The  
22 term ‘reprocessed medical device’ means a device  
23 that—

24                   “(A) is labeled for single use, or is dispos-  
25                   able and intended for single use; and

1           “(B) is cleaned or sanitized after use in  
2           order that such a device may be reused upon  
3           another individual.

4           “(2) REPROCESSING.—The term ‘reprocessing’  
5           means a procedure employed in order to produce a  
6           reprocessed medical device.”.

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